UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC, NOVARTIS PHARMACEUTICALS CORP., and VETTER PHARMA INTERNATIONAL GMBH, Defendants.	Case No. 1:20-CV-05502-AJN **Oral Argument Requested**

MEMORANDUM OF LAW IN SUPPORT OF NOVARTIS'S MOTION TO DISMISS FIRST AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM

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TABLE OF ABBREVIATIONS

’631 Patent	Novartis’s U.S. Patent No. 9,220,631
Anti-VEGF	Pharmaceutical product that treats the overproduction of vascular endothelial growth factor
EYLEA	Regeneron’s EYLEA® (aflibercept) injection, which is sold in vials and in pre-filled syringes
EYLEA PFS	Regeneron’s EYLEA injection, as sold in pre-filled syringes
FAC	Regeneron’s First Amended Complaint, Dkt. 88
FDA	U.S. Food & Drug Administration
ITC	International Trade Commission
ITC action	Novartis’s patent infringement proceeding against Regeneron in the ITC, captioned *In re Certain Pre-Filled Syringes For Intravitreal Injection & Components Thereof*, USITC Pub. 715158 (July 21, 2020)
LUCENTIS	Genentech’s LUCENTIS® (ranibizumab) injection, which is sold in vials and in pre-filled syringes
LUCENTIS PFS	Genentech’s LUCENTIS, as sold in pre-filled syringes
NDNY	Northern District of New York
NDNY action	Novartis’s patent infringement suit against Regeneron in the NDNY, captioned *Novartis Pharma AG v. Regeneron Pharms., Inc.*, No. 1:20-cv-00690-TJM-CFH (N.D.N.Y.)
Novartis	Defendants Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corp.
PFS	Pre-filled syringe
PTO	U.S. Patent & Trademark Office
Regeneron	Plaintiff Regeneron Pharmaceuticals, Inc.
VEGF	Vascular endothelial growth factor, a naturally occurring protein in the human body, the overproduction of which can cause serious eye diseases

Vetter	Defendant Vetter Pharma International GmbH

I. INTRODUCTION

Four months ago, Defendants moved to dismiss Regeneron's original complaint for failure to adequately plead any claim for relief. Now, the First Amended Complaint does not cure any of Regeneron's pleading defects; it merely compounds them. The essence of Regeneron's new allegations is that Novartis defrauded the PTO by failing to disclose that an unnamed Vetter employee co-invented technology claimed in Novartis's '631 Patent, as part of a devious plot to deprive *Regeneron* of its purported ownership rights in that patent under Regeneron's separate contract with Vetter. In other words, Regeneron now insists that it has an ownership stake in a patent it claims should never have issued in the first place. This newly concocted theory confirms that Regeneron's action is just the other side of the coin to Novartis's patent infringement case, and that—as argued in Defendants' original pending motion to dismiss, transfer, or stay—Regeneron should have filed its claims, if at all, in the NDNY.

This Court should dismiss Regeneron's Amended Complaint for the reasons stated in Defendants' prior Rule 12(b)(6) briefing, and then some.

First, Regeneron's new inventorship-fraud antitrust claim (Count IV) fails because Regeneron does not plead with particularity (i) that anyone at Vetter actually co-invented the '631 Patent; (ii) that Novartis fraudulently concealed Vetter's alleged co-inventorship with intent to deceive the PTO; and (iii) that the '631 Patent would have not issued but for Novartis's alleged omission. Regeneron instead alleges that if Novartis had disclosed the supposed, unnamed Vetter inventors, the patent *still* would have issued—Regeneron just would have owned part of it. That is the exact opposite of what a "*Walker Process* fraud" claim requires, and in no way satisfies the stringent pleading standards that inequitable-conduct claims impose.

Second, Regeneron's theory that Defendants conspired to conceal Vetter's co-inventorship of the '631 Patent (asserted in Count III) fails because Regeneron does not plead

facts plausibly demonstrating that Novartis and Vetter hatched that supposed scheme. To the contrary, to support its new conspiracy allegation, Regeneron merely speculates that it *makes sense* that Novartis and Vetter would have agreed to conceal Vetter's contributions to the patent because [redacted]. But simply telling the Court its theory of *why* Novartis and Vetter might have reached an agreement is a far cry from a cognizable conspiracy claim. And without more, Regeneron's new conspiracy claim fails.

Third, Regeneron's assertion that Novartis tortiously interfered with the Regeneron–Vetter contract (Count V) fails because Regeneron does not plead with plausibility or particularity that Novartis actually *knew* of the contractual terms with which Novartis allegedly interfered. All Regeneron alleges is that Novartis *should* have guessed that Vetter and Regeneron had an agreement [redacted] because terms like that are allegedly "common in the industry." Inference stacking is not enough to state a claim for tortious interference.

Fourth, Regeneron's claims fail for all the reasons discussed in Novartis's prior briefing. The First Amended Complaint still does not adequately allege (i) that Novartis has monopoly power—or even that Novartis competes—in a cognizable antitrust market; (ii) the existence of a conspiracy to limit anti-VEGF PFS products; (iii) that Novartis substantially foreclosed access to PFS filling services; (iv) that Regeneron could have or would have entered the alleged relevant market at any earlier date, but for Defendants' alleged conduct; and (v) that any of Regeneron's claims are timely under the applicable statutes of limitations.

For all the above reasons, this Court should dismiss Regeneron's First Amended Complaint with prejudice.

II. FACTUAL BACKGROUND

This motion incorporates the alleged facts as described in Novartis's prior briefing. *See* Mot. to Dismiss 4-7, Dkt. 56 ("Mot."). A summary of Regeneron's allegations is as follows:

On December 29, 2015, the PTO issued the '631 Patent to Novartis. FAC ¶ 9. The '631 Patent claims, among other things, a terminally sterilized pre-filled syringe (or "PFS") with "an ophthalmic solution [that] comprises a VEGF antagonist." *Id.* ¶ 96. In other words, the '631 Patent claims specialized syringes (and methods of treatment using that syringe) for injecting medicine into patients' eyes to treat the overproduction of a protein that causes serious eye diseases. *Id.* ¶¶ 33, 96. Anti-VEGF products can be packaged in PFS form or vials; whereas a PFS comes pre-packaged with the medicine in the syringe, vials require ophthalmologists to draw medicine from the vial into a syringe before use. *Id.* ¶¶ 76-77. Both delivery mechanisms carry the same product.

On June 19, 2020, Novartis filed patent infringement actions against Regeneron in the NDNY and the ITC, alleging that Regeneron's EYLEA PFS product infringes the '631 Patent. *Id.* ¶ 137. The NDNY action is stayed—at Regeneron's request—but the ITC case is proceeding apace, with trial scheduled for April 2021.[1] On July 17, 2020, Regeneron brought this separate action—in the wrong Court—alleging that Novartis obtained the '631 Patent by fraud and that Novartis's patent suits are part of a scheme to exclude Regeneron from the market. Dkt. 1.

Defendants moved to dismiss, transfer, or stay this action under the first-to-file rule, Dkt. 40, and sought dismissal of Regeneron's complaint for failure to state a claim, Dkts. 55, 56, 58. After those motions were fully briefed, and *after* Regeneron's amended pleading deadline had passed, Regeneron filed a First Amended Complaint on January 25, 2021. Dkt. 88.

This new pleading does not affect Defendants' motion to dismiss, transfer, or stay. If anything, Regeneron's new inventorship allegations—which closely mirror one of Regeneron's defenses in the ITC case—only *further* underscore the degree to which this antitrust case

[1] *See* Dkt. 41 at 2-3; Order Modifying Procedural Schedule, at 3, *Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof*, Inv. No. 337-TA-1207 (Dec. 10, 2020) (Order No. 20).

overlaps with the patent actions, providing yet additional reasons why this Court should grant the motion to dismiss, transfer, or stay. If the Court grants that motion, it need not decide this one.

III. LEGAL STANDARD

To survive a motion to dismiss, a plaintiff must plead facts that allow the court to "reasonabl[y] infer[] that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).[2] This requires "sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Id.* A complaint "armed with nothing more" than "labels and conclusions" does not cut it. *Id.* at 678-79. So too, a complaint that pleads facts that are "merely consistent with" a defendant's liability "stops short of the line between possibility and plausibility." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). And allegations "that are contradicted by the complaint itself" are not plausible. *Perry v. NYSARC, Inc.*, 424 F. App'x 23, 25 (2d Cir. 2011).

A plaintiff alleging fraud must also satisfy Rule 9(b), *Swierkiewicz v. Sorema N. A.*, 534 U.S. 5096, 513 (2002), which requires the plaintiff to "state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b). This means a plaintiff has to "explain why the statements were fraudulent," *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993), identify the speaker, *DiMuro v. Clinique Labs*., *LLC*, 572 F. App'x 27, 30 (2d Cir. 2014), and state "where and when the statements were made," *Signify N. Am. Corp. v. Reggiani Lighting USA, Inc.*, 2020 WL 1331919, at *3 (S.D.N.Y. 2020). Put simply, Rule 9(b) requires the "who, what, when, where, and how of the alleged fraud." *Id.*

IV. ARGUMENT

Regeneron's First Amended Complaint does not plead *any* claim with plausibility, much

[2] Unless otherwise noted, all emphasis is added and internal citations and quotations are omitted.

less with particularity. Not only are Regeneron's new allegations conclusory, the First Amended Complaint does nothing to cure the deficiencies Defendants identified in the original Complaint. This Court should dismiss each of Regeneron's five Counts under Rule 12(b)(6). With respect to Regeneron's new allegations and claims:

- ***First***, Regeneron fails to plead with particularity (i) that anyone at Vetter actually co-invented the '631 Patent, (ii) that Novartis fraudulently concealed Vetter's alleged co-inventorship with intent to deceive the PTO examiner, and (iii) that the '631 Patent would not have issued, but for the alleged omission (Count IV).

- ***Second***, Regeneron fails to plead with plausibility that Novartis conspired with Vetter to fraudulently conceal Vetter's alleged co-inventorship of the '631 Patent from Regeneron (Count III).

- ***Third***, Regeneron fails to plead with plausibility or particularity that Novartis knew of Regeneron's purported ownership rights in the '631 Patent under the Regeneron–Vetter [redacted], as required to state a claim for tortious interference with contract (Count V).

Defendants' existing Rule 12(b)(6) motions to dismiss, which Novartis incorporates by reference,[3] apply with full force to the First Amended Complaint. As Defendants demonstrated in that briefing, Regeneron's claims should be dismissed for the following reasons:

- ***Fourth***, Regeneron still fails to plausibly allege that Novartis has monopoly—or any—power in a cognizable antitrust market (Counts I, II, III, IV).

- ***Fifth***, Regeneron still fails to plausibly allege facts establishing the existence of an overarching conspiracy to limit anti-VEGF PFS products (Count III).

- ***Sixth***, Regeneron still fails to plausibly allege that Novartis harmed competition because it does not plead that defendants foreclosed access to PFS filing services (Counts II and III).

- ***Seventh***, Regeneron still fails to plausibly allege antitrust injury because it does not plead facts showing that it intended and was prepared to enter the purported relevant market at any earlier date (Counts II and III).

- ***Eighth***, Regeneron's claims are still untimely because it did not bring its claims

[3] To minimize duplicative briefing, the parties stipulated, and this Court ordered, that "Defendants may incorporate by reference briefing on their original Rule 12(b)(6) motions to dismiss." Dkt. 85.

within the applicable limitations periods (all Counts).

The Court should dismiss the action in full, without leave to amend. *See O'Neill v. Std. Homeopathic Co.*, 346 F. Supp. 3d 511, 534 (S.D.N.Y. 2018) (dismissing complaint with prejudice where, as here, the plaintiff had already amended its complaint once).

A. Regeneron Fails To Plead With Particularity That Novartis Fraudulently Concealed Vetter's Alleged Co-Inventorship With Specific Intent To Deceive The PTO Examiner (Count IV).

Regeneron's new *Walker Process* claim (Count IV) is based on nothing more than naked assertions and stacked inferences. Here's the theory: Novartis—supposedly but inexplicably aware of a contract between Regeneron and Vetter that [redacted] —omitted Vetter's employee(s) from the listed inventors on the '631 Patent application, all to "conceal" Vetter's contributions and to "sabotage Regeneron's ownership rights." FAC ¶ 10. Regeneron does not support this fanciful theory with particularized factual allegations (or any facts for that matter), as Rule 9(b) and the antitrust laws require. On this basis alone, Regeneron's Count IV is doomed.

A "party attempting to plead inequitable conduct faces a daunting task." *Town & Country Linen Corp. v. Ingenious Designs LLC*, 2020 WL 3472597, at *6 (S.D.N.Y. 2020). If anything, pleading *Walker Process* fraud is even more demanding. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069-70 (Fed. Cir. 1998). Regeneron must allege "with particularity" (1) that Novartis deliberately made a false representation or omitted a material fact (2) with a specific intent to deceive the patent office, (3) that the patent examiner relied on that misrepresentation or omission in granting the patent, and (4) that "but for" the misrepresentation or omission, "the patent would not have been granted." *In re DDAVP Direct*

Purchaser Antitrust Litig., 585 F.3d 677, 685 (2d Cir. 2009).[4] Regeneron does no such thing.

- ***First***, Regeneron says Novartis concealed "the Vetter inventor(s)," FAC ¶ 10, but fails to identify a single Vetter "inventor." Nor does Regeneron identify the subject of any Vetter "invention." Since Regeneron does not plead that anyone at Vetter was an inventor, it has not alleged that Novartis omitted anything.

- ***Second***, Regeneron does not plead (because it cannot) that Novartis's intent in the alleged concealment of the "Vetter inventor(s)" was specifically to deceive the PTO. Regeneron points to its own contract with Vetter as supplying the motivation to deceive, but Regeneron never explains how Novartis would have even known that Regeneron was working with Vetter, let alone the details of the provisions of a confidential contract between those companies.

- ***Third***, Regeneron does not even *try* to allege that the '631 Patent would not have issued but for the alleged omission, an essential element of the claim.

1. Regeneron Does Not Plead With Particularity That Novartis Omitted Vetter's Alleged Co-Inventorship.

Regeneron does not plead with particularity that Novartis omitted Vetter's alleged co-inventorship to the PTO. Regeneron never identifies any Vetter inventors, much less what he, she or they purportedly invented—which is fatal in itself.[5] Regeneron hangs its inventorship theory on a single line in Novartis and Vetter's [redacted] FAC ¶ 280.[6] Regeneron would have this Court believe that this statement is enough to surmount the "heavy" presumption that "the named [Novartis] inventors are the true and only inventors." *Gen. Elec. Co. v. Wilkins*, 750 F.3d 1324, 1329 (Fed. Cir. 2014).

It is not. There are two aspects to invention: conception and reduction to practice. *See*

[4] Regeneron must also plausibly allege the traditional elements of a Sherman Act, Section 2 claim, including monopoly power in a properly defined relevant market. *See DDAVP*, 585 F.3d at 686-87.

[5] *See Dror v. Kenu, Inc.*, 2019 WL 5684520, at *13 (N.D. Cal. 2019) (dismissing complaint when plaintiff alleged that defendant omitted co-inventor but complaint "provide[d] no additional details about who [the inventor was]" or "what relationship (if any)" he or she had to the patent at issue).

[6] The [redacted] that Regeneron cites is no matter. FAC ¶ 142. It states only that [redacted]. *Id.* Regeneron does not identify anyone at Vetter who it claims was responsible for the conception of [redacted].

Cooper v. Goldfarb, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Conception—the "touchstone of inventorship"—is the "formation" of "a definite and permanent idea of the complete and operative invention" in one's mind. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). Reduction to practice requires "the discovery that an invention actually works." *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994); *see Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997) ("[A]n inventor must establish that he actually prepared the composition and knew it would work."). To be a joint inventor, reduction to practice is insufficient: a "joint inventor must contribute to *conception*." *CODA Dev. S.R.O. v. Goodyear Tire & Rubber Co.*, 916 F.3d 1350, 1358 (Fed. Cir. 2019).

Regeneron fails to allege the "touchstone" of inventorship—facts showing that Vetter "conceived" of the inventions claimed in the '631 Patent. *CODA*, 916 F.3d at 1358. Claiming that Vetter [redacted] says nothing about *conception* of the claimed inventions—and therefore does not establish inventorship—regardless of whether the [redacted] FAC ¶ 12.[7] Of course, even if [redacted] *were* enough to show invention (it is not), Regeneron's Count IV would still fail because Regeneron's ambiguous allegation that "at least one Vetter employee" contributed to the '631 Patent, FAC ¶ 139, does not identify the "who, what, when, where, and how" of the alleged fraud. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). *What* specifically was invented, and by *whom*? Regeneron does not say.

These deficiencies are fatal where, as here, Regeneron does not allege that the "essential information lies uniquely within another party's control." *Id.* at 1330. Nor could it. Regeneron

[7] *See, e.g., Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1576-77 (Fed. Cir. 1996) (affirming summary judgment against inequitable conduct defense where alleged co-inventor "planted the seed" and was "involved in the invention development process," but did not "conceive[] the idea").

cannot claim ignorance of the alleged inventors; Regeneron itself emphasizes that Vetter "worked with Regeneron for approximately eight years" on the alleged inventions. FAC ¶ 260. If anyone at Vetter invented anything in the course of that "collaboration," *id.* ¶¶ 166-67, Regeneron never explains why (and does not plead any facts suggesting) it would not have known about it. Given Regeneron's "long-standing relationship" with Vetter, *id.* ¶ 152, Regeneron must do more than simply claim that "someone" at Vetter was an inventor. *See Exergen Corp.*, 575 F.3d at 1330. That alone requires dismissal: without alleging that any specific Vetter employee was an "inventor," Regeneron cannot plead with particularity that Novartis concealed Vetter's inventorship.[8]

2. Regeneron Fails To Plead With Particularity That Novartis Knew About Vetter's Inventorship And Purposefully Omitted That Information With A Specific Intent To Deceive The Patent Office.

The Court should also dismiss Regeneron's Count IV for the independent reason that Regeneron fails to "allege facts that give rise to a strong inference of fraudulent intent." *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995). To allege fraudulent intent, Regeneron must "plead the event which [it] claim[s] [gave] rise to an inference of knowledge." *DDAVP*, 585 F.3d at 695. This may include allegations "as to who possessed knowledge," "when and how they obtained that knowledge," and "why they should have known of the fraud." *Id.* Here, that means Regeneron would have to allege particular facts showing that Novartis knew about the alleged fraud—*i.e.*, that specific individuals at Vetter were "inventors" under patent law—and that Novartis individuals with duties to disclose to the PTO omitted the inventorship information

[8] *See, e.g.*, *Brixham Sols. Ltd. v. Juniper Networks, Inc.*, 2014 WL 250204, at *5-7 (N.D. Cal. 2014) (dismissing inequitable conduct claim when plaintiff failed to "identif[y] the specific individual or individuals who allegedly co-invented the claimed invention" or the "specific facts showing how each [person]" contributed); *Accordant Energy, LLC v. Vexor Tech, Inc.*, 2018 WL 7412753, at *5 (N.D. Ohio 2018) (dismissing inequitable conduct claim because defendant "fail[ed] to identify an individual inventor" and "any specific contribution" by that inventor).

with the specific intent to deceive the PTO.

Regeneron does not allege any facts of the sort laid out in *DDAVP*. Instead, Regeneron lists 13 people who could *possibly* have a duty to disclose material information to the patent office (Novartis's named inventors and prosecuting attorneys) and broadly concludes that, *a fortiori*, "at least . . . one or more" of them must have known about Vetter's inventorship and "deliberately withheld" that information from the patent office. FAC ¶ 138. That "lacks the specificity that Rule 9(b) demands." *Signify N. Am. Corp.*, 2020 WL 1331919, at *6.

Regeneron has to identify "a specific individual" who "knew of the withheld material information or of the falsity of the material misrepresentation." *Exergen Corp.*, 575 F.3d at 1328; *see Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) ("In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference."). It is not enough simply to allege that Novartis or "its agents and/or attorneys" made the omissions, *Exergen Corp.*, 575 F.3d at 1329, or to offer a laundry list of possible options, as Regeneron does, *see Signify N. Am. Corp.*, 2020 WL 1331919, at *6 (striking inequitable conduct defense where defendant alleged that "Lys, Morgan, 'and/or' Teja withheld the information," because "and/or" made it "entirely possible" that the named individuals "might not be the individuals who acted with intent to deceive"); *see also Town & Country Linen Corp*, 2020 WL 3472597, at *7 (dismissing inequitable conduct defense when defendant identified named inventors and prosecuting attorneys but failed to allege specific facts showing that any specific individuals knew omitted information was required to be disclosed).

What is more, Regeneron does not plead facts showing that Novartis knew about the terms of the *confidential* Regeneron–Vetter contract, which supposedly spurred Novartis's

"inventorship deception." FAC ¶¶ 10-11. Regeneron chalks up Novartis's presumed knowledge to "industry practice," alleging that Novartis should have known the specific terms of Regeneron's contract because of what is common in the industry. *Id.* ¶ 164. But this argument fails at the outset because Regeneron does not plead facts showing that Novartis knew Regeneron and Vetter were working together or that there was a contract. And even if that had been alleged, alleging knowledge of "industry practice" is insufficient to plead knowledge of specific circumstances with particularity. *Acito*, 47 F.3d at 52; *see Medtech Prods. Inc. v. Ranir, LLC*, 596 F. Supp. 2d 778, 796 (S.D.N.Y. 2008) (allegation that defendant was "a sophisticated entity well aware of the industry practice" was insufficient to show knowledge of contract). As such, for this additional reason, this Court should dismiss Count IV.

3. Regeneron Fails To Plead With Particularity That But For The Alleged Omission The PTO Would Not Have Granted The Patent.

Regeneron's Count IV fails for a third independent reason: Regeneron does not allege that the PTO would not have granted the '631 Patent but for Novartis's alleged omission. To plead *Walker Process* fraud, a plaintiff must allege that "but for" the "misrepresentation or deliberate omission," "the patent would not have been granted." *DDAVP*, 585 F.3d at 685. This requirement derives from foundational antitrust principles; as the Second Circuit explains, "whether a patent could be issued matters more than who would possess it; if a patent could still 'have been issued to someone,' its market power would still have been concentrated (properly) in one party." *Id.* at 693 (quoting *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984) ("If the invention is patentable, it does not matter from an antitrust standpoint what skullduggery the defendant may have used to get the patent issued or transferred to him.")).

Regeneron does not allege that "but for" Novartis's alleged non-disclosure of Vetter's inventorship, the PTO would not have granted the patent. Just the opposite: Regeneron states

that if Novartis had disclosed Vetter's employees as co-inventors, the '631 Patent *still* would have issued (disregarding the alleged nondisclosure of material prior art, which underpins Regeneron's other *Walker Process* claim[9]); the only difference is that Regeneron supposedly would have enjoyed "contractual ownership rights" in the patent. FAC ¶¶ 282-84. And so, because Regeneron does not (and cannot) allege that "but for" Novartis's "deliberate omission" of Vetter's inventorship, "the patent would not have been granted," *DDAVP*, 585 F.3d at 685, Regeneron's Count IV must be dismissed for failure to state a claim.[10]

And even if Regeneron's own theory did not foreclose a materiality argument (it plainly does), Regeneron still could not allege materiality because it fails to plead that had the PTO known of Vetter's alleged inventorship, Novartis could not have just corrected the error. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 132-34 (Fed. Cir. 1998) (explaining that "to avoid inadvertent invalidity," patent law "permits correction of the designated inventorship of a patent when an error was made without deceptive intent"); *see Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1556 (Fed. Cir. 1997) (same).

Any one of these three reasons is enough to dismiss Regeneron's new *Walker Process* fraud claim. Together, they make the case for dismissal overwhelming.

B. Regeneron Fails To Plead A Conspiracy To Conceal Vetter's Contributions To The '631 Patent Because It Does Not Plead Any Direct Or Circumstantial Facts Evidencing An Agreement to Conceal Inventorship (Count III).

Regeneron began this litigation by alleging an implausible conspiracy between Novartis

[9] Because each claim must stand on its own, *see Iqbal*, 556 U.S. at 679, Regeneron cannot rely on allegations supporting its first *Walker Process* claim (Count I) to save its second *Walker Process* claim (Count IV).

[10] *See, e.g.*, *Allflex USA, Inc. v. Avid Identification Sys., Inc.*, 2010 WL 11405130, at *11-12 (C.D. Cal. 2010) (finding that allegations could not "support *Walker Process* fraud as a matter of law" because even if defendant had "disclosed the additional inventors . . . the patentability of the claims would have been the same"); *Correct Craft IP Holdings, LLC v. Malibu Boats, LLC*, 2010 WL 598693, at *7 (M.D. Fla. 2010) (dismissing *Walker Process* claim because plaintiff failed to show that "the patent would not have issued *but* for the patent examiner's justifiable reliance on the false declarations of inventorship") (emphasis in original); *Air Liquide Am. Corp. v. MG Nitrogen Servs., Inc.*, 1999 WL 35809350, at *3 (D.N.M. 1999) (same).

and Vetter to control the global supply of anti-VEGF products. *See* Mot. 15-17. Now, eight months later, Regeneron doubles down and concocts a *second* conspiracy theory: that Novartis and Vetter agreed to conceal Vetter's co-inventorship of the '631 Patent, so as "to circumvent Regeneron's intellectual property ownership rights [redacted]" with Vetter. FAC ¶ 259. As Novartis has previously explained, *see* Mot. 15-17, Regeneron must "allege enough facts to support the inference that a conspiracy actually existed." *Mayor & City Council of Balt., Md. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013). This requires allegations of "direct or circumstantial evidence" establishing that Novartis and Vetter shared a "conscious commitment to a common scheme designed to achieve an unlawful objective." *Anderson News LLC v. Am. Media, Inc.*, 680 F.3d 162, 184 (2d Cir. 2012).

Despite now having access to Vetter and Novartis's contracts, Regeneron does not plead any direct evidence of this supposed conspiracy to conceal Vetter's inventorship. *Cf. Citigroup*, 709 F.3d at 136 (noting that direct evidence refers to a "smoking gun"). Who hatched this inventorship conspiracy, what did they specifically agree upon, and when and how did they do it? Regeneron does not say. *See LaFlamme v. Societe Air Fr.*, 702 F. Supp. 2d 136, 147-48 (E.D.N.Y. 2010) ("direct evidence" requires plaintiff to plead the "'specific time, place, or person' involved in the alleged conspirac[y]") (quoting *Twombly*, 550 U.S. at 565 n.10).

Nor does Regeneron offer "circumstantial evidence" that makes conspiracy any more plausible. Regeneron claims [redacted] is "powerful evidence" that they conspired years earlier to conceal Vetter's inventorship. FAC ¶ 187. But that agreement—[redacted] *id.* ¶ 186—is entirely consistent with lawful conduct: a licensor and licensee may agree [redacted][11]

[11] *See Alfred E. Mann Found. For Sci. Rsch. v. Cochlear Corp.*, 604 F.3d 1354, 1358 (Fed. Cir. 2010) (explaining that a "patent owner may transfer all substantial rights in the patents-in-suit," which "confer[s] standing to sue");

See Iqbal, 556 U.S. at 678 ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'"). Regeneron does not plead *facts* supporting an inference that this efficient, commonsense arrangement was a cover for a plot to conceal Vetter's inventorship.

Fundamentally, Regeneron's new conspiracy does not make any sense. Regeneron asserts that Vetter helped contribute to the '631 Patent, that Regeneron [redacted], and that Vetter tried to keep Regeneron in the dark about Vetter's inventions. But Regeneron's allegations only *contradict* that conclusion. Regeneron concedes that Vetter *specifically told Regeneron* that it and Novartis had settled an IP ownership dispute related to anti-VEGF PFS technology, and in so doing provided Regeneron with a list of patent applications, including the one that *became the '631 Patent*. *See* Dkt. 67-1; FAC ¶¶ 9, 166, 170. That patent application became public in January 2014,[12] and the patent issued in December 2015. FAC ¶ 282. In the First Amended Complaint, Regeneron purports to line up the '631 Patent's claims with work Vetter supposedly performed [redacted]—a comparison Regeneron could have done the second the application became public. *Id.* ¶ 143.

If Vetter were trying to conceal its supposed co-inventorship from Regeneron, none of these allegations make any sense. Taking them as true, Vetter did the *opposite* of "concealing" its involvement with the '631 Patent: it informed Regeneron of the IP ownership dispute and gave Regeneron everything it needed to line up the work Vetter allegedly performed for Regeneron with Novartis's patent claims. This is the very definition of implausibility.

Because Regeneron does not plead any direct or circumstantial facts evidencing a

see, e.g., *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1383 (Fed. Cir. 2015) (parties agreed to "grant [licensee] the right to enforce" patent and "pursue infringement litigation").

[12] *See* U.S. Patent Application No. 2014/0012227 A1 (published Jan. 9, 2014).

conspiracy to conceal Vetter's alleged inventorship, this Court should dismiss Regeneron's Count III to the extent it rests on this newfound conspiracy theory.

C. Regeneron Fails To Plead With Particularity That Novartis Tortiously Interfered With The Regeneron-Vetter Contract Because It Does Not Establish That Novartis Knew About The Contract's Existence (Count V).

Regeneron's First Amended Complaint accuses Novartis of tortiously interfering with the Regeneron–Vetter [redacted]. FAC ¶¶ 287-89. To plead tortious interference under New York law,[13] Regeneron must allege "(1) the existence of valid contract between the plaintiff and a third party; (2) defendant's knowledge of that contract, (3) defendant's intentional procurement of the third-party's breach of the contract without justification, (4) actual breach of the contract, and (5) damages resulting therefrom." *Rich v. Fox News Network, LLC*, 939 F.3d 112, 126-27 (2d. Cir. 2019). Because its tort claim is premised on allegations of fraud, FAC ¶¶ 285-94, Rule 9(b)'s heightened pleading standard applies. *GWG MCA Cap., Inc. v. Nulook Cap., LLC*, 2019 WL 1084777, at *9 (E.D.N.Y. 2019).

Regeneron's tortious-interference claim does not satisfy *Twombly*, much less Rule 9. That is because Regeneron does not allege that Novartis had "actual knowledge of the terms of [the Regeneron–Vetter] contract and of the contractual obligation that was allegedly breached." *See State St. Glob. Advisors Tr. Co. v. Visbal*, 431 F. Supp. 3d 322, 348 (S.D.N.Y. 2020). While Regeneron need not allege that Novartis had "perfect or precise knowledge," it must *at least* offer facts establishing that Novartis actually knew about the contract itself and [redacted]. *Id.* Regeneron does not.

As noted, all Regeneron alleges is that Novartis *must have* known that Regeneron and Vetter had a contract [redacted] because those sorts of provisions are "common in the

[13] Regeneron does not identify the relevant state law; Novartis will assume that New York law applies.

industry," and because Novartis somehow knew Regeneron was a Vetter customer. FAC ¶¶ 162-64. These vague allegations cannot support a tortious-interference claim. Take, for example, *Medtech Products, Inc. v. Ranir, LLC*. The plaintiff there alleged that the defendant "knew or should have known" about a contract because the defendant was "a sophisticated entity well aware of the industry practice of securing [such] agreements." 596 F. Supp. 2d at 796. The court rejected that "wholly conclusory" allegation. *Id.* at 797. In so doing, it noted that the plaintiff's "general claim" of knowledge based on industry practice was insufficient to establish that the defendant was actually "aware" of the contract's terms, as the tort requires. *Id.*

Regeneron's allegations fare no better than those the *Medtech* court found wanting. Just like in *Medtech*, Regeneron bases its allegation that Novartis knew about the Regeneron–Vetter contract on the assertion that these sorts of contracts are "common in the industry." FAC ¶ 164. If alleging knowledge of a contract based on supposed industry practice is insufficient to satisfy *Twombly*, as *Medtech* holds, it most certainly falls short of satisfying Rule 9(b)'s heightened pleading standards. This Court must dismiss Regeneron's Count V for failure to state a claim.

D. Regeneron Fails To Cure Any Of The Original Complaint's Deficiencies.

1. Regeneron Still Fails To Plausibly Allege That Novartis Possesses Monopoly Power—Or Any Power—In A Properly Defined Relevant Market (Counts I, II, III, And IV).

Regeneron's First Amended Complaint does nothing to cure the original complaint's most fundamental shortcoming: in a case alleging that Novartis is trying to *monopolize* a pharmaceutical market, Regeneron does not plausibly allege that Novartis possesses monopoly power—or even that it *competes*—in any properly defined relevant market. As explained in Novartis's prior motion, this failure is fatal to all of Regeneron's antitrust claims. Mot. 8-15.

Regeneron's First Amended Complaint only cements the implausibility of Regeneron's purported "anti-VEGF PFS" market: Regeneron still does not plead facts establishing a lack of

reasonable substitutability or the absence of cross-elasticity of demand between anti-VEGF vials and PFS products, as it is required to do. *See Chapman v. N.Y. State Div. for Youth*, 546 F.3d 230, 237-38 (2d Cir. 2008).[14] Regeneron's only new allegations are a handful of excerpts from the ITC claim-construction hearing, in which an expert witness noted that PFS products "can be administered with fewer steps," which "reduce[s] the likelihood of infection" and "time required for the procedure." FAC ¶¶ 196-97. Those allegations run into the same problem Novartis identified in its prior briefing: Regeneron does not plead facts that show that any supposed differences in terms of quality or convenience actually render PFS products and vials non-interchangeable. Mot. 8-15; *see Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 576-78 (S.D.N.Y. 2011) (alleged two-drug market was implausible where complaint acknowledged other treatments but did not sufficiently plead lack of substitutability).

If anything, Regeneron pleads the opposite. Case in point: Regeneron concedes that "[o]nce a PFS launches, physicians rapidly convert[] their patients from the vial version to the PFS version at a rate of approximately 80% to 90%." FAC ¶ 88. Regeneron likewise recognizes that if EYLEA PFS were not available, patients could switch to EYLEA *vials*. *Id.* ¶ 21. In admitting that vials and PFSs are reasonable substitutes, Regeneron dooms its purported PFS-only market: Regeneron admits that vials and PFSs are reasonable substitutes. *See Downtown Music Publ'g LLC v. Peloton Interactive, Inc.*, 436 F. Supp. 3d 754, 765-66 (S.D.N.Y. 2020) (granting motion to dismiss based on party's own admission of substitutability).

If that were not enough, Regeneron still fails to allege that *Novartis* even competes in the purported relevant market. Mot. 13-14. It is undisputed that the alleged monopolist must be the

[14] *See, e.g.*, *LLM Bar Exam, LLC v. Barbri, Inc.*, 271 F. Supp. 3d 547 (S.D.N.Y. 2017) (dismissing for failure to explain why products used for the same purposes were not "reasonably interchangeable"); *Mooney v. AXA Advisors, LLC*, 19 F. Supp. 3d 486, 499 (S.D.N.Y. 2014) (dismissing antitrust claims were complaint failed to "provide a discussion of cross-elasticity of demand").

firm that possesses monopoly power. *See United States v. Aluminum Co. of Am.*, 148 F.2d 416, 432 (2d Cir. 1945) (Hand, J.); *H.L. Hayden Co. of N.Y. v. Siemens Med. Sys. Inc.*, 879 F.2d 1005, 1018 (2d Cir. 1989). Yet, as Regeneron acknowledges, *Genentech* sells LUCENTIS PFS in the United States. FAC ¶ 52. It does not matter that Novartis owns a minority share in Genentech's parent corporation, *id.* ¶ 53, that Novartis contributed to LUCENTIS PFS's "development," *id.* ¶ 48, or that Genentech has a license to the '631 Patent, *id.* ¶ 54. Mot. at 14; *see, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 2009 WL 678631, at *7-8 (E.D. Pa. 2009) (dismissing antitrust claim when defendant collaborated with its licensee "to bring a single product to the market" and received "royalties on [the licensee's] profits from sales" but did not itself sell the product). Regeneron has not pleaded any basis for disregarding corporate form and imputing Genentech's LUCENTIS PFS sales to Novartis.

Even if Regeneron could impute Genentech's LUCENTIS PFS sales to Novartis, the First Amended Complaint still fails to allege that Genentech or Novartis has *any* share of the alleged anti-VEGF PFS market. Mot. 13. Instead of alleging LUCENTIS PFS's market share in the First Amended Complaint, Regeneron just confirms that its prior omission was no mistake: Regeneron once again alleges only that LUCENTIS PFS has an unspecified but supposedly "significant" market share. FAC ¶ 226. That alone warrants dismissal. Mot. 13.[15]

This Court should dismiss each of Regeneron's antitrust claims—Counts I, II, III, IV—because Regeneron does not plausibly allege that Novartis possesses monopoly power.

[15] *See Apotex Corp. v. Hospira Healthcare India Private Ltd.*, 2020 WL 58247, at *6-7 (S.D.N.Y. 2020) (dismissing attempted monopolization claim for failure to plausibly allege at least "some degree of market power"); *Radiancy, Inc. v. Viatek Consumer Prods. Grp., Inc.*, 138 F. Supp. 3d 303, 323-24 (S.D.N.Y. 2014) (allegation that defendant had a "very substantial market share" was "conclusory"; dismissing *Walker Process* counterclaim).

2. Regeneron Still Fails To Allege Any Direct Or Circumstantial Facts Evidencing An Overarching Conspiracy To Limit The Supply of Anti-VEGF Products (Count III).

This Court must dismiss Regeneron's conspiracy claim (Count III) in full because, in addition to not pleading a plausible conspiracy to conceal Vetter's alleged inventorship, the First Amended Complaint does not plead any new facts evidencing a conspiracy to "control[] the total supply of all anti-VEGF PFS treatments." FAC ¶ 171. For the reasons stated in Novartis's prior briefing, Regeneron fails to plausibly allege that Novartis and Vetter had a "conscious commitment" to this supposed "unlawful scheme." Mot. 15-17.

The First Amended Complaint only confirms the futility of Regeneron's conspiracy allegations. For instance, despite now having access to Defendants' contracts, Regeneron does not supply *any* new facts showing that Novartis and Vetter agreed to demand exclusivity from any of Vetter's customers, much less from Regeneron. To the contrary: the Vetter sublicense offer that Regeneron submitted to this Court (and which it incorporated in its pleadings) does not include any exclusivity demand. *See* Dkt. 67-1. Regeneron quotes liberally from Defendants' contracts, yet it does not identify *any* provision by which Vetter "assured" Novartis that it would require Regeneron to enter a "long-term, exclusive supply relationship" with it, as Regeneron accuses Vetter of doing. FAC ¶ 157. And in fact, as the sublicense offer shows, Vetter offered Regeneron a *royalty-free* license. Dkt. 67-1. Offering Regeneron a royalty-free license on non-exclusive terms is inconsistent with any alleged conspiracy to keep Regeneron out of the market, and the First Amended Complaint does nothing to resolve this conflict.

Because Regeneron's new allegations do nothing to salvage its conspiracy claim, the Court should dismiss Count III for the reasons stated in Novartis's prior briefing. Mot. 15-17.

3. Regeneron Still Fails To Allege Harm To Competition Because It Does Not Plead That Defendants Foreclosed Access To PFS Filling Services (Counts II And III).

As explained in Novartis's prior motion, Regeneron fails to allege that Novartis and Vetter foreclosed competition in the alleged anti-VEGF PFS market—which is essential to its theories under Counts II and III—because Regeneron does not allege any facts showing that Defendants locked up "so large a percentage" of the PFS filling services market that competition was "unreasonably constricted." Mot. 17-18 (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 284 (3d Cir. 2012)). The First Amended Complaint does not solve that problem. Just the opposite, Regeneron's new complaint only confirms that Regeneron had PFS filling options aside from Vetter: Regeneron re-alleges that it opted not to accept Vetter's sublicense offer precisely because it wanted the option to work with other PFS fillers. *See* FAC ¶ 15 (Regeneron "could not" agree to exclusivity with Vetter because of purported "concerns about Vetter as its sole PFS filler"). And that is what Regeneron ultimately did. Thus, for the reasons laid out in Novartis's prior briefing, *see* Mot. 17-20, this Court must dismiss Counts II and III.

4. Regeneron Still Fails To Allege Antitrust Injury Because It Does Not Plead Facts Showing That It Intended And Was Prepared To Enter The Purported Market At Any Earlier Date (Counts II And III).

Counts II and III must also be dismissed because Regeneron's First Amended Complaint does nothing to cure Regeneron's failure to plausibly allege that EYLEA PFS would have launched any earlier had Defendants not allegedly denied Regeneron access to PFS filling services. *See* Mot. 20-21. Without any factual allegations showing that Regeneron would have been prepared to launch EYLEA PFS any earlier, Regeneron cannot establish any antitrust injury. *Id.* And that failure is fatal. *See Zenith Radio Corp. v. Hazeltime Rsch., Inc.*, 395 U.S. 101, 128 (1969) (plaintiff must show that it "intended to and was prepared to enter the [relevant] market during the damage period"); *see, e.g.*, *Spring Pharms., LLC v. Retrophin, Inc.*, 2019 WL

6769988, at *13-14 (E.D. Pa. 2019) (dismissing claims where plaintiff failed to "adequately plead that it ha[d] taken sufficient affirmative steps to enter the market"). This Court must therefore dismiss Counts II and III. *See* Mot. 20-21.

5. Regeneron's Claims Are Still Untimely Because It Did Not Sue Within The Applicable Limitations Periods (All Counts).

Finally, Regeneron's First Amended Complaint underscores an inconvenient reality for Regeneron: it filed its claims too late. Regeneron again concedes that it first suffered an alleged injury in "late 2013," when Vetter allegedly "cut off Regeneron" and Regeneron supposedly "was forced to invest significant time, money, and effort to establish a new, reliable supply chain for EYLEA PFS." FAC ¶¶ 166, 175. Since the applicable limitations periods for Regeneron's antitrust and tortious-interference claims began ticking when it first suffered any alleged injury,[16] those claims all accrued in ***2013***. Mot. 21-25. By failing to file its claims within the requisite four years (three years for the tort claim[17]), Regeneron abandoned them.

a. <u>The Continuing Violation Doctrine Does Not Apply Because Regeneron Had Knowledge Of Its Purported Claims In 2013 And Does Not Plead Any New And Independent Overt Acts.</u>

Apparently recognizing that its original complaint provided no basis for escaping the statute of limitations, Regeneron now tries to add something new to the story: it alleges that Novartis and Vetter "undertook a new overt act in furtherance of their anticompetitive conspiracy" when, [redacted] FAC ¶ 18. This "overt act," Regeneron says, allowed Novartis to prosecute infringement claims without [redacted] *Id.*

[16] *See Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190-91 (1997) (antitrust); *Kronos, Inc. v. AVX Corp.*, 81 N.Y.2d 90, 94 (1993) (tortious interference).
[17] C.P.L.R. § 214; *Kronos, Inc.*, 81 N.Y.2d at 92.

Labeling something an "overt act" does not make it so. *See Twombly*, 550 U.S. at 555 ("[A] plaintiff's obligation to provide the grounds for his entitle[ment] to relief requires more than labels and conclusions."). To the contrary, binding precedent confirms that the [redacted] —even as described by Regeneron—was *not* a "new and independent" act sufficient to restart the clock, but rather a "reaffirmation" or "manifestation of the prior overt act of entering into the [alleged 2013] contract." *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 68-69 (2d Cir. 2019). Regeneron asserts that in 2013, Defendants conspired [redacted] FAC ¶ 10. According to Regeneron, the purpose of the [redacted] was to *continue* concealing [redacted] and the existence of the conspiracy. *Id.* ¶ 18. Reaffirmations do not keep the limitations period running. *US Airways*, 938 F.3d at 68-69.[18]

Even setting that aside, the [redacted] could not toll the limitations period because Regeneron does not allege that the [redacted] caused any "new and accumulating injury." *See US Airways, Inc.*, 938 F.3d at 68 (new overt act restarts the limitations period only if it "inflict[s] new and accumulating injury on the plaintiff"). In fact, Regeneron does not identify *any* injury (old, new, or otherwise) stemming from the [redacted]. Absent any "new and accumulating injury," the continuing violations doctrine does not apply, and this Court must dismiss Regeneron's claims as untimely.

[18] *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 229 (E.D.N.Y. 2003) (finding payment "contemplated by, and needed to implement" underlying agreement merely reaffirmed contract); *Vitale v. Marlborough Gallery*, 1994 WL 654494, at *5 (S.D.N.Y. 1994) ("If an initial refusal to deal is final," a plaintiff's "subsequent unsuccessful efforts to deal with the defendant" does not restart the statute of limitations.).

b. The Fraudulent Concealment Doctrine Does Not Apply Because Regeneron Does Not Plead With Particularity That Extraordinary Circumstances Prevented It From Earlier Filing Its Claims.

Regeneron also attempts to salvage its untimely claims by alleging that Defendants "fraudulently concealed the scope of their anticompetitive agreement from Regeneron" until December 23, 2020, when Defendants produced [redacted]. FAC ¶ 272. Regeneron insists that, until then, it had no way of knowing about "Defendants' agreement to conceal the Vetter employees' inventorship." *Id.* ¶ 273. That defies both law and common sense.

To plead equitable tolling on the basis of fraudulent concealment, Regeneron must allege (1) that Novartis and Vetter "concealed the existence of [their] unlawful conduct," (2) that Regeneron "remained ignorant of the violation until sometime within the statute of limitations," and (3) that "this continuing ignorance was not the result of a lack of diligence." *Levy v. BASF Metals Ltd.*, 2017 WL 2533501, at *8 (S.D.N.Y. 2017). This doctrine applies in only "rare and exceptional circumstances." *Smith v. McGinnis*, 208 F.3d 13, 17 (2d. Cir. 2000). And, like any other fraud claim, it "must be pleaded with particularity." *Levy*, 2017 WL 2533501, at *8.

Most basically, Regeneron's fraudulent concealment theory cannot succeed because Regeneron does not (and cannot) plead that it "remained ignorant of the violation until sometime within the statute of limitations." *Id.* Regeneron raised an improper-inventorship defense in the ITC case in *August 2020*, months before it received the production that supposedly put it on notice of the alleged fraud. Dkt. 42-3, at 19-20 (¶¶ 16-17). As Regeneron told the ITC, the '631 Patent should be declared invalid "to the extent the invention claimed in the '631 Patent was derived from Vetter and/or Regeneron employees" pursuant to the Regeneron–Vetter collaboration, "which included agreements regarding development of intellectual property." *Id.* ¶ 17. Regeneron cannot plead that "extraordinary circumstances prevented [it] from filing a

complaint on time" where its own actions show that it knew of Vetter's supposed inventorship well before December 2020. *Levy*, 2017 WL 2533501, at *8.[19]

So too, Regeneron's fraudulent concealment allegations fail because Regeneron does not plead particularized facts demonstrating that, despite acting with reasonable diligence, it could not discover the facts underlying its new inventorship accusation. *Smith*, 208 F.3d at 17. Because "[r]easonable diligence is a prerequisite to the application of equitable tolling," *Koch v. Christie's Int'l PLC*, 699 F.3d 141, 157 (2d Cir. 2012), Regeneron "must plead that it was reasonably diligent in investigating fraud to claim the benefit of equitable tolling," *Ferring B.V. v. Allergan, Inc.*, 4 F. Supp. 3d 612, 632 (S.D.N.Y 2014) (rejecting motion to amend complaint because allegations would fail under 12(b)(6)). Regeneron does not do so.

If anything, the First Amended Complaint undermines any assertion of diligence. As noted above, Regeneron concedes that *in 2013*, Vetter specifically informed Regeneron that it had settled a dispute with Novartis concerning "ownership" of a patent application family, and that Vetter specifically disclosed the '631 Patent application to Regeneron. *See supra* at 14; FAC ¶¶ 9, 166. That patent issued in December 2015. FAC ¶ 282. "The existence of a patent application or a public patent puts parties on notice of their existence." *Zirvi v. Flatley*, 433 F. Supp. 3d 488, 459-60 (S.D.N.Y. 2020). Regeneron was indisputably aware of the '631 Patent.

In the First Amended Complaint, Regeneron attempts to demonstrate its purported ownership rights in the '631 Patent by lining up the patent's claims with [redacted] *See* FAC ¶¶ 143-49. According to Regeneron,

[19] *See Harper v. Ecole*, 648 F.3d 132, 137 (2d Cir. 2011) ("The term 'extraordinary' refers . . . to the severity of the obstacle impeding compliance with a limitations period."); *see also, e.g.*, *Parada v. Banco Industrial De Venezuela, C.A.*, 753 F.3d 62, 71 (2d Cir. 2014) (rejecting equitable tolling argument when plaintiff's own actions "showed that she was capable of taking legal action" earlier); *Zirvi v. Flatley*, 433 F. Supp. 3d 448, 463 (S.D.N.Y. 2020) (rejecting equitable tolling argument when "facts alleged . . . undermine[d] any argument that the plaintiffs" did not have notice of potential violations).

the '631 Patent claims "a 1 mL prefilled syringe" that meets certain specifications, and [redacted] and well before Novartis filed the application on January 25, 2013, that became the '631 Patent." *Id.* ¶ 148. Because of that, Regeneron says, the invention [redacted] *Id.*

These allegations put to rest any assertion that Regeneron could not have discovered the facts underlying its claims. Regeneron tacitly admits that it had at its fingertips *everything* it needed to do this comparison as soon as the patent application became public. There is no reason Regeneron could not have evaluated the '631 Patent application in light of [redacted] and reached the same conclusion it reaches now: that [redacted]. *Id.* Regeneron's failure to connect the dots that Vetter had placed in front of its eyes falls far short of reasonable diligence.[20]

Because Regeneron does not plead that it exercised reasonable diligence in discovering "the facts surrounding the patent," *Greenberg v. Miami Children's Hosp. Rsrch. Inst., Inc.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003), it fails to plead the "extraordinary circumstances" that equitable tolling requires, *Valverde v. Stinson*, 224 F.3d 129, 134 (2d Cir. 2000).[21]

V. CONCLUSION

For these reasons, this Court should dismiss Regeneron's First Amended Complaint.

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[20] *See Klang v. Pflueger*, 2014 WL 4922401, at *6 (C.D. Cal. 2014) (dismissing complaint where plaintiff "pled no facts" showing "his inability to discover these applications following their publication despite reasonable diligence"); *Greenberg v. Miami Children's Hosp. Rsch. Inst., Inc.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003) ("plaintiffs could have undertaken due diligence to uncover the facts surrounding the patent" after it issued).

[21] Even if Regeneron had adequately pleaded fraudulent concealment, it would not save Regeneron's causes of action unrelated to inventorship. For example, Regeneron does not plead fraudulent concealment in connection with Novartis's supposed nondisclosure of prior material art, the basis for Count I. Nor does it plead fraudulent concealment in connection with its original conspiracy theory. For good reason: those claims have nothing to do with Vetter's alleged concealed inventorship.

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